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Schneider, David ; Schober, Florian ; Grohmann, Philipp ; Hammerle, Christoph H F ; Jung, Ronald E

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DOI: <https://doi.org/10.1111/clr.12327>

Posted at the Zurich Open Repository and Archive, University of Zurich

ZORA URL: <https://doi.org/10.5167/uzh-96096>

Journal Article

Accepted Version

Originally published at:

Schneider, David; Schober, Florian; Grohmann, Philipp; Hammerle, Christoph H F; Jung, Ronald E (2015). In-vitro evaluation of the tolerance of surgical instruments in templates for computer-assisted guided implantology produced by 3-D printing. *Clinical Oral Implants Research*, 26(3):320-325.

DOI: <https://doi.org/10.1111/clr.12327>

In-vitro evaluation of the tolerance of surgical instruments in templates for computer-assisted guided implantology produced by 3D printing

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Keywords: Dental implants, guided surgery, 3D-Printing

Number of Figures: 9

Number of Tables: 2

Abstract

Objective: The aim of this *in-vitro* study was to compare the tolerance of surgical instruments in surgical guides produced by 3D printing, without metal sleeves to a surgical guide with conventional metal sleeves from two different manufacturers.

Materials and methods: Lateral movements of drill tips caused by tolerance between the sleeve and drill key and between the drill key and the drill were recorded after application of a standardized force to the surgical instruments. Four groups were tested: Control 1 (C1): Metal sleeve from commercially available surgical system 1; Test 1 (T1): 3D-printed sleeve for surgical system 1; Control 2 (C2): Metal sleeve from commercially available surgical system 2. Test 2 (T2): 3D-printed sleeve for surgical system 2.

Results: The mean total lateral movement was 0.75mm (0.5 to 1.04mm) in the C1 group and 0.91mm (0.54 to 1.34mm) in the C2 group. The mean amount of movement from tolerance between sleeve and drill-guiding key was 0.31mm (range 0.22 to 0.41mm) in C1 and 0.42mm (range 0.29 to 0.56mm) in C2. This lateral movement was in mean reduced by 0.24mm (32%) in T1 and by 0.39mm (43%) in T2 group. This reduction was statistically significant in both groups ($p < 0.001$).

Conclusion: The tolerance of surgical instruments and the lateral movements of the drills were significantly reduced by the use of 3D printing with reduced sleeve diameter. This reduction could improve the over all accuracy in computer-assisted template guided implant dentistry. The lateral movement of the drill can be further reduced by using a shorter drill and a higher drill key. This can be considered during implant planning and CAD/CAM of surgical guides.

Introduction

Computer-assisted implant planning and template guided implant placement (CAIP) is a novel technology applying digital technologies in dentistry. In the past, numerous systems for planning and template production have been developed and are commercially available. The introduction of cone beam computer tomography (CBCT) and its increasing application in the dental field has widened the indication for 3-dimensional radiographic examination, also in connection with preoperative implant surgery planning (Nitsche, et al. 2011).

Basically, there are two different workflows for surgical template production. With some systems, the radiographic template containing information on the prosthetic set-up are manually produced by a dental technician. After recording the CT-image and determination of the future implant position in the planning software, the template is modified with the use of coordinate tools. An instrument guiding metal sleeve is attached in the corresponding position in the surgical guide. During implant bed preparation, this metal sleeve will serve as a guidance for drill-guiding drill keys that will be inserted into the sleeve. Also, the implant mount will be guided by this sleeve during implant insertion.

Other systems use the digital planning data for CAD/CAM production of a surgical guide by rapid prototyping. Usually the same kind of metal sleeves are incorporated into the guide as in guides produced by a dental technician.

Numerous preclinical and clinical studies reporting on the accuracy of computer-assisted template guided surgery have been published (Ozan, et al. 2009) (Sarment, et al. 2003) (Di Giacomo, et al. 2005) (Van Assche, et al. 2007). Systematic reviews on computer-assisted implant dentistry, including studies on accuracy, revealed mean deviations between the planned to the effectively reached implant position of approximately 1mm at the implant shoulder and 1.5mm at the apex of the implant (Schneider, et al. 2009) (Jung, et al. 2009). Possible sources of errors resulting in deviations of the final implant position can be found at various stages within the workflow. Up to date, little knowledge is present on the origin and exact amount of inaccuracies within the different steps of the workflow.

In a recent in-vitro study a marked tolerance of the surgical instruments was reported (Van Assche & Quirynen 2010). In that study, lateral movements of the instrument tip of up to 2.7mm were recorded if the drills were actively moved within their guides. It is possible, that the deviations reported in accuracy studies partially result from unwanted movements of surgical components within their guiding sleeves. Therefore, a reduction of this tolerance could increase the overall accuracy of computer-assisted template-guided implant dentistry. Recently, 3D printing has become popular in industrial application. Due to its relatively low costs and its high precision this technology has also been introduced for surgical guide production from biocompatible acrylate materials. These surgical guides can be designed and/or modified by the use of computer-aided design (CAD) software.. This allows to eliminate the incorporation of metal guiding sleeves and possibly to decrease the tolerance between the printed sleeves and the drill-guiding keys.

The **objective** of this *in-vitro* study is to compare the tolerance of surgical instruments in surgical guides produced by 3D printing, without metal sleeves to a surgical guide with conventional metal sleeves from two different manufacturers.

Materials and Methods

The present study was performed at the facilities of the Center for dental medicine of the University of Zürich. It was designed as a controlled *in-vitro* study involving four study groups:

Control Group 1 (C1):

Metal sleeve, drill keys and drills from the Astra Facilitate Guided Surgery System (Astra Tech Dental, Mölndal, Sweden) were used in this group. The sleeve height was 4 mm, the inner diameter 4.7 mm. Drill-guiding keys were 1, 2, 3 and 4 mm in height, the diameter of the part that is inserted into the sleeve is 4.6 mm. Drills of 18, 22 and 25 mm in length and 3.2 mm in diameter were used (Figures 1 and 2)

Control Group 2 (C2):

Metal sleeve, drill keys and drills from the Straumann Guided Surgery System (Institut Straumann AG, Basel, Switzerland) were used in this group. The sleeve height was 5 mm, the inner diameter 5 mm. Drill-guiding keys were 1 and 3 mm in height, the diameter of the part that is inserted into the sleeve is 4.85 mm. Drills of 16, 20 and 24 mm in length and 3.5 mm in diameter were used (Figures 1 and 3).

Test Group 1 (T1):

3D-Printed sleeves for the drill keys and drills from the Astra Facilitate Guided Surgery System (Astra Tech Dental, Mölndal, Sweden) were used in this group. The inner diameter of the sleeve was computer-designed with a diameter of 4.75 mm. The same instruments were applied as in control group 1. (Figures 1 and 2)

Test Group 2 (T2):

3D-Printed sleeves for the drill keys and drills from the Straumann Guided Surgery System (Institut Straumann AG, Basel, Switzerland) were used in this group. The inner diameter of

the sleeve was computer-designed with a diameter of 5.02 mm. The same instruments were applied as in control group 2. (Figures 1 and 3)

A T-shaped 4 mm thick device containing two holes simulating a surgical guide was designed using a CAD-Software (Swissmeda medical applications, Zurich, Switzerland) and fabricated from acrylate material (exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate) by 3D-printing (Objet Ltd., Rehovot, Israel)(Figure 1). The diameter of the hole measured 6.4 mm (C1) or 6.3 mm (C2) at the control site in order to receive the standard metal sleeve provided by the manufacturer. At the test sites, the diameters of the holes have been designed to receive only the drill-guiding keys without additional metal sleeves. The respective diameters of the holes were 5.7 mm at test 1 (T1) and 5.05 mm at test (T2). The hole diameters at the test sites were evaluated during a pilot study to reduce instrument tolerance but still to ensure adequate handling of surgical drill keys and implant mounts for guided implant placement.

Subsequently, the original metal sleeve provided by the implant manufacturer was pressed and glued into the prefabricated canal at the control sites. Scaled paper was then firmly attached to the device serving as reference in the background for later measurements (Figures 1, 4 and 5).

The printed device containing the test and control sleeves was then firmly attached to a table.. Surgical drill keys and drills from standard surgical kits were then inserted into the sleeves according the recommended surgical protocol. The drills were held by a surgical hand piece.

With these instruments in place, a standardized controlled force was applied on the drill key containing the drill to provoke the maximum lateral movement of the drill tip in the surgical components. Based on the calculation (length of the lever arm x weight used to perform the movement) a standardized torque of 4.2 Ncm was applied for the lateral movement, both to

the left and right, Standardized photographs were performed capturing the position of the bur tip in its mostly deflected position to either side.

The same torque was then applied on the hand piece to provoke movement of the drill within the drill key, without movement of the drill key within the sleeve which was stabilized. Again, a photograph was taken. This way, two measurements could be obtained: One measurement of the movement of the drill keys within the sleeves, another measurement of the movement of the drill within the drill key (Figure 4).

In the same manner a series of photographs was taken using different drill key and drill dimensions for all four groups (Tables 1 and 2).

The photographs were imported and superimposed using a software program (Photoshop Elements 6, Adobe). The superimposed semi-transparent images were then imported into another software for linear measurements (ImageJ, National Institute of Health, USA).

Calibration of the length measured within the software was performed using the scaled paper in the background of each photograph. After applying x25 magnification measurements of the lateral deviation at the tip of the surgical drill were performed in the software (Figure 5). Movements resulting from tolerance between the drill key and the sleeve as well as the drill and the drill key were measured. The total movement was calculated by adding these two values. The relative amount of the movement within the components was calculated in relation to the total movement.

Descriptive **statistics** were applied to quantify the amount of lateral movements resulting from tolerance of the drill key in the sleeve and the drill in the drill key for all four groups. SPSS Version 20 (IBM Armonk, NY, USA) was used for statistical analysis and Prism Version 6 (Graph Pad Software, La Jolla, USA) to generate graphs. In addition, the proportion of the drill key movement within the sleeve was calculated for the whole lateral movement of the instruments in all groups.. Non-parametric Wilcoxon Signed-Rank Test for matched-pairs was applied for evaluation of the reduction of instrument tolerance of the test

with respect to the control group as measured by tolerance drill key-to-sleeve. Results of statistical analysis with p-values <0.05 were considered statistically significant.

Results

The results of the measurements are summarized in tables 1 and 2 and Figures 6 to 9. The lateral movements of the tip of the drills were dependent on the drill length and the drill key height. The longer the drill and the shorter the drill key, the more pronounced were the lateral movements.

In **control group 1** (n=12), the mean lateral movement of the tip of the drill caused by tolerance between **drill key and sleeve** amounted to 0.31 mm (median 0.32, range 0.22 to 0.41 mm). This means a relative tolerance of 42% of the total instrument tolerance (i.e. amount of movement of drill in drill-key plus amount of movement of drill-key in sleeve). The movement of the drill within the drill key was in mean 0.44 mm (median 0.45, range 0.28-0.63 mm). The mean total lateral movement resulted in 0.75 mm (median 0.76, range 0.5 to 1.04 mm).

In the **test 1 group** (n=12) the mean tolerance between **drill key and sleeve** was 0.04 mm (median 0.05, range 0.01-0.08 mm). This is equivalent to 9% of the total instrument tolerance. The movement of the drill within the drill key was in mean 0.46 mm (median 0.49, range 0.27-0.65 mm). The mean total instrument tolerance amounted to 0.51 mm (median 0.53, 0.34 to 0.69 mm). Compared to the control group 1, the total lateral tolerance in the test 1 group was significantly **reduced by 0.24 mm or by 32%** ($p < 0.001$) with 95% CI (0.20 mm, 0.28 mm) and minimum 0.16 mm and maximum 0.35 mm.

In the **control group 2** (n=6), the mean lateral movement of the tip of the drill caused by tolerance between **drill key and sleeve** amounted to 0.42 mm (median 0.41, range 0.29 to 0.56 mm). This means a relative tolerance of 47% of the total instrument tolerance. The movement of the drill within the drill key was in mean 0.49 mm (median 0.46, range 0.25-0.77 mm). The mean total lateral movement resulted in 0.91 mm (median 0.89, 0.54 to 1.34 mm).

In the **test 2 group** (n=6) the mean tolerance between **drill key and sleeve** was 0.03 mm (median 0.03, range 0.02-0.04 mm). This is equivalent to 7% of the total instrument tolerance. The movement of the drill within the drill key was in mean 0.49 mm (median 0.46, range 0.25-0.77 mm). The mean total instrument tolerance amounted to 0.52 mm (median 0.50, 0.3 to 0.81 mm).

Compared to the control group 2, the total lateral tolerance in the test 2 group was again significantly **reduced by 0.39 mm or by 43%** (p=0.03) with 95% CI (0.26 mm, 0.54 mm) and minimum 0.24 mm and maximum 0.53 mm.

Discussion

The present in-vitro study showed that the tolerance of surgical instruments and therefore the amount of lateral movement of drills can be significantly reduced by using a modified protocol for surgical guide production. This protocol includes CAD and the use of 3D printing for surgical guide production without the use of any metal sleeves and with a more intimate contact between the guide and the drill-guiding drill key. The amount of lateral movement due to tolerance between the sleeve and the drill key was reduced by 32% in test 1 group and by 43% in test 2 group.

For geometric reasons, the amount of lateral movement at the tip of the drill also depends on the length of drills and drill keys. A longer guiding channel was found to be reducing the angular deviations of implants in an in-vitro investigation (Choi, et al. 2004). Based on the lever principle, longer drills exhibit more lateral movement. Longer drill keys lead to a longer guidance of the drill within the drill key and therefore the lateral movement of the drill is reduced. Also, the movement between the drill key and the sleeve seems to be reduced by increasing drill key height. However, this is related to the fact that the drill length is virtually reduced by the amount of the sleeve height. In summary, the amount of lateral movement could be reduced by the use of shorter drills and higher drill keys in all four groups. Other components possibly influencing the movement, the height of the guiding sleeve and its distance from the prospective implant shoulder were not evaluated in the present study. Keeping in mind the geometric aspects, less movement will result if the sleeve is positioned more apically and closer to the future implant shoulder. However, the apical position of the sleeve is limited due to possible interference of the sleeve with the mucosa or the alveolar bone.

The movements of the surgical instruments in this study were provoked in the full range allowed by the components. In clinical use the instruments are usually held in a more

passive, central position. Under simulated ideal conditions a recent in-vitro study comparing the influence of different heights of guides on accuracy of implant placement did not show significant differences between 4, 6 and 8mm high guidance, if instruments were kept in central position within the surgical components (Park, et al. 2009). In some situations, however, a passive guidance of the instruments may be difficult or impossible. This includes limited access and difficult insertion of the instruments due to impaired mouth opening. When drilling on oblique cortical surfaces, like on partially resorbed alveolar ridges or incompletely healed alveolae, instruments can also be deflected from their central position. Therefore, the investigational set-up is realistic and may be representative to many clinical situations. However, the impact on clinical outcomes using the presented altered manufacturing protocol for surgical guides still has to be investigated in a clinical study.

An important fact is that up to now it remains unclear to what extent a deviation of the actually reached implant position from the planned position can be acceptable, since the impact of deviation depends on the anatomical situation, tooth or gap size, prosthetic aim etc.

One of the advantages of computer-assisted, template guided implant dentistry is the instrument guidance during implant bed preparation and implant insertion. Therefore, its use has been suggested to be indicated in situations, where manual free-hand drilling is difficult, e.g. in the anterior esthetic zone with incomplete alveolar healing or alveolar ridge resorption (Hammerle, et al. 2009). The lower the tolerance of the surgical components would be, the better guidance would result. The tolerance between the rotating drills and the drill keys can hardly be reduced due to mechanical friction and debris. However, the tolerance within the sleeves bears the potential for reduction. A certain degree of tolerance, however, has to be maintained to ensure proper insertion of the drill keys and to allow rotation of the implant mounts. The amount of tolerance depends on the surgical system used.

With the use of CAD and 3D printing, this tolerance can be easily modified according to the used surgical components. Among the various options in rapid prototyping 3D printing has

several advantages. Compared to other technologies in rapid prototyping (e.g. stereolithography, milling, selective laser sintering etc.) it is relatively low priced and therefore could be used even in smaller institutions such as dental laboratories or dental practices. With the printer used in the present investigation, a slice thickness of 16µm can be achieved resulting in a high printing resolution. A large variety of acrylic materials with different colors and mechanical properties can be used and objects made from several materials can be printed, including biocompatible materials. This technology has the potential for widespread use for medical and non-medical application. It has already been used for manufacturing of orthognatic splints (Metzger, et al. 2008) and models for craniomaxillary anatomy reconstruction (Silva, et al. 2008) (Ibrahim, et al. 2009).

The conclusions based on the present study are limited due to its in-vitro design. It remains unknown, if the forces applied on the instruments in the present study are identical with forces occurring in clinical use. Also, only two surgical systems using a similar set-up of surgical instruments were tested. Systems using different surgical instrumentarium might exhibit different lateral tolerance values. Unfortunately, no drills of the same diameter were available from the manufacturers to exclude a possible influence of the drill diameter. Other factors possibly causing deviations like movements causes by improper occlusal or mucosal rest or deformation of the surgical guide were excluded on purpose in the present investigation. In the clinic, these and other factors can further contribute to deviations of the implant position from the initial plan and have to be investigated separately.

Conclusion

The tolerance of surgical instruments and the lateral movements of the drills were significantly reduced by the use of 3D printing with reduced sleeve diameter. This reduction could improve the over all accuracy in computer-assisted template guided implant dentistry. The lateral movement of the drill can be further reduced by using a shorter drill and a higher

drill key. This can be considered during implant planning and CAD of surgical guides.

Passive fit of drilling instruments should be aimed for during surgery.

Acknowledgements

The authors would like to acknowledge the support of Malgorzata Roos in statistical analysis.

Conflict of interest

The study was initiated and funded by Clinic for Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Switzerland. One of the co-authors (FS) is member of the advisory board of the Swissmeda Company. There are no conflicts of interest.

Tables

			Metal sleeve (group C1)	% of total tolerance	Printed sleeve (group T1)	% of total tolerance
Drill key-sleeve	Drill 18mm	Drill key 1mm	0.27	36 %	0.02	4 %
		Drill key 2mm	0.26	38 %	0.04	9 %
		Drill key 3mm	0.24	43 %	0.01	3 %
		Drill key 4mm	0.22	44 %	0.03	8 %
	Drill 22mm	Drill key 1mm	0.37	41 %	0.03	5 %
		Drill key 2mm	0.33	43 %	0.06	11 %
		Drill key 3mm	0.30	43 %	0.05	11 %
		Drill key 4mm	0.29	45 %	0.06	13 %
	Drill 25mm	Drill key 1mm	0.41	39 %	0.06	9 %
		Drill key 2mm	0.36	41 %	0.07	10 %
		Drill key 3mm	0.35	43 %	0.04	8 %
		Drill key 4mm	0.34	43 %	0.08	13 %
		Mean	0.31	42 %	0.04	9 %
Drill-drill key	Drill 18mm	Drill key 1mm	0.48	64 %	0.49	96 %
		Drill key 2mm	0.41	62 %	0.42	91 %
		Drill key 3mm	0.31	57 %	0.33	97 %
		Drill key 4mm	0.28	56 %	0.32	92 %
	Drill 22mm	Drill key 1mm	0.53	59 %	0.53	95 %
		Drill key 2mm	0.44	57 %	0.48	89 %
		Drill key 3mm	0.39	57 %	0.40	89 %
		Drill key 4mm	0.35	55 %	0.37	87 %
	Drill 25mm	Drill key 1mm	0.63	61 %	0.63	91 %
		Drill key 2mm	0.51	59 %	0.58	90 %
		Drill key 3mm	0.47	57 %	0.52	92 %
		Drill key 4mm	0.45	57 %	0.50	87 %
		Mean	0.44	58 %	0.46	91 %
Total	Drill 18mm	Drill key 1mm	0.76	100 %	0.51	67 %
		Drill key 2mm	0.67	100 %	0.46	69 %
		Drill key 3mm	0.55	100 %	0.34	62 %
		Drill key 4mm	0.50	100 %	0.34	68 %
	Drill 22mm	Drill key 1mm	0.90	100 %	0.56	62 %
		Drill key 2mm	0.76	100 %	0.54	70 %
		Drill key 3mm	0.69	100 %	0.45	65 %
		Drill key 4mm	0.64	100 %	0.42	66 %
	Drill 25mm	Drill key 1mm	1.04	100 %	0.69	67 %
		Drill key 2mm	0.87	100 %	0.65	74 %
		Drill key 3mm	0.82	100 %	0.56	68 %
		Drill key 4mm	0.79	100 %	0.58	74 %

		Mean	0.75	100 %	0.51	68 %
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Table 1: Mean lateral tolerance in group T1 and C1 indicated in millimeters.

			Metal sleeve (group C2)	% of total tolerance	Printed sleeve (group T2)	% of total tolerance
Drill key-	Drill 16mm	Drill key 1mm	0.34	44 %	0.02	5 %
		Drill key 3mm	0.29	53 %	0.04	12 %
	Drill 20mm	Drill key 1mm	0.43	40 %	0.02	4 %
		Drill key 3mm	0.40	51 %	0.04	10 %
	Drill 24mm	Drill key 1mm	0.56	42 %	0.04	5 %
		Drill key 3mm	0.51	51 %	0.04	7 %
		Mean	0.42	47 %	0.03	7 %
Drill-drill key	Drill 16mm	Drill key 1mm	0.42	56 %	0.41	95 %
		Drill key 3mm	0.25	47 %	0.26	88 %
	Drill 20mm	Drill key 1mm	0.64	60 %	0.59	96 %
		Drill key 3mm	0.38	49 %	0.40	90 %
	Drill 24mm	Drill key 1mm	0.77	58 %	0.76	95 %
		Drill key 3mm	0.49	49 %	0.51	93 %
		Mean	0.49	53 %	0.49	93 %
Total	Drill 16mm	Drill key 1mm	0.76	100 %	0.43	57 %
		Drill key 3mm	0.54	100 %	0.30	55 %
	Drill 20mm	Drill key 1mm	1.06	100 %	0.61	57 %
		Drill key 3mm	0.78	100 %	0.44	56 %
	Drill 24mm	Drill key 1mm	1.34	100 %	0.81	60 %
		Drill key 3mm	1.00	100 %	0.55	55 %
		Mean	0.91	100 %	0.52	57 %

Table 2: Mean lateral tolerance in group T2 and C2 indicated in millimeters.

Figures

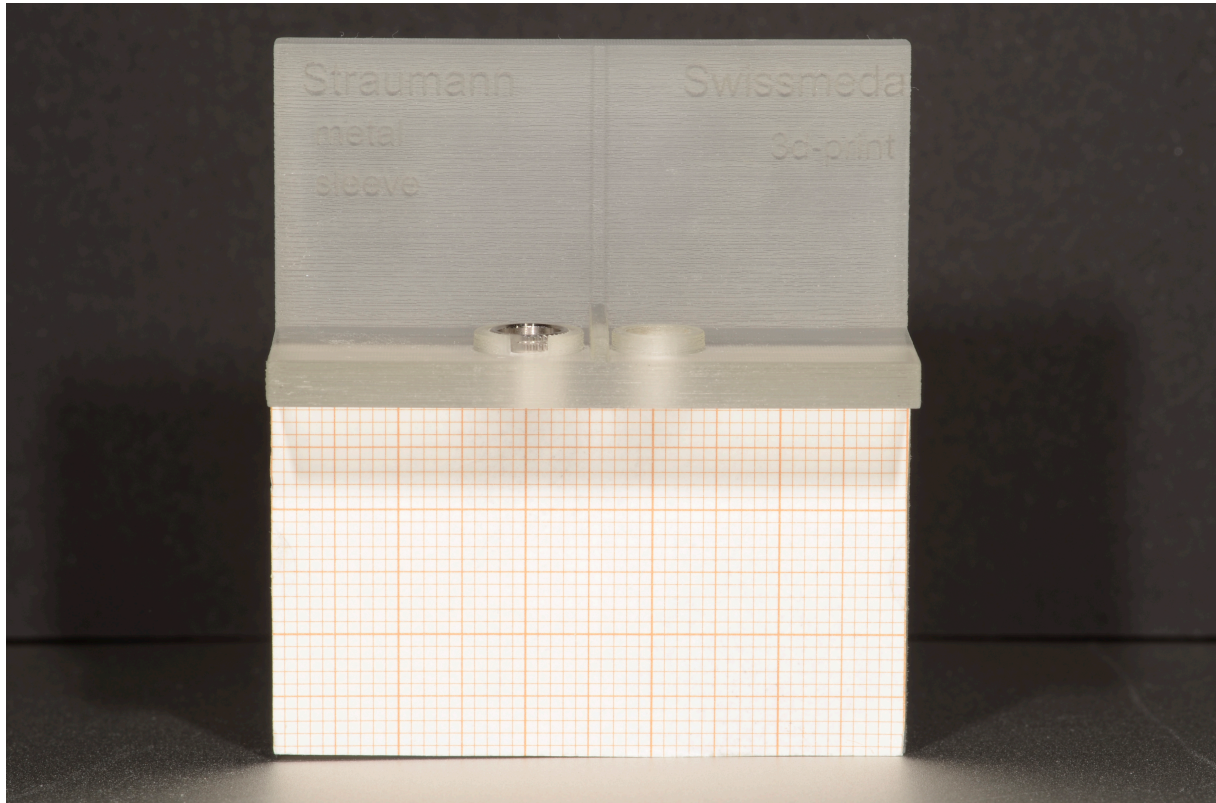


Figure 1: Study set-up. A standard metal sleeve is incorporated in the left control site, no metal sleeve is present in the printed test site at the right. The same set-up was used for Test 1/Control 1 and Test 2/Control 2, with the respective sleeves corresponding to the surgical system.



Figure 2: Surgical system used in control 1 and test 1 group: Drills of 18, 22 and 25 mm in length and drill guides of 1, 2, 3 and 4 millimeters in height were used.

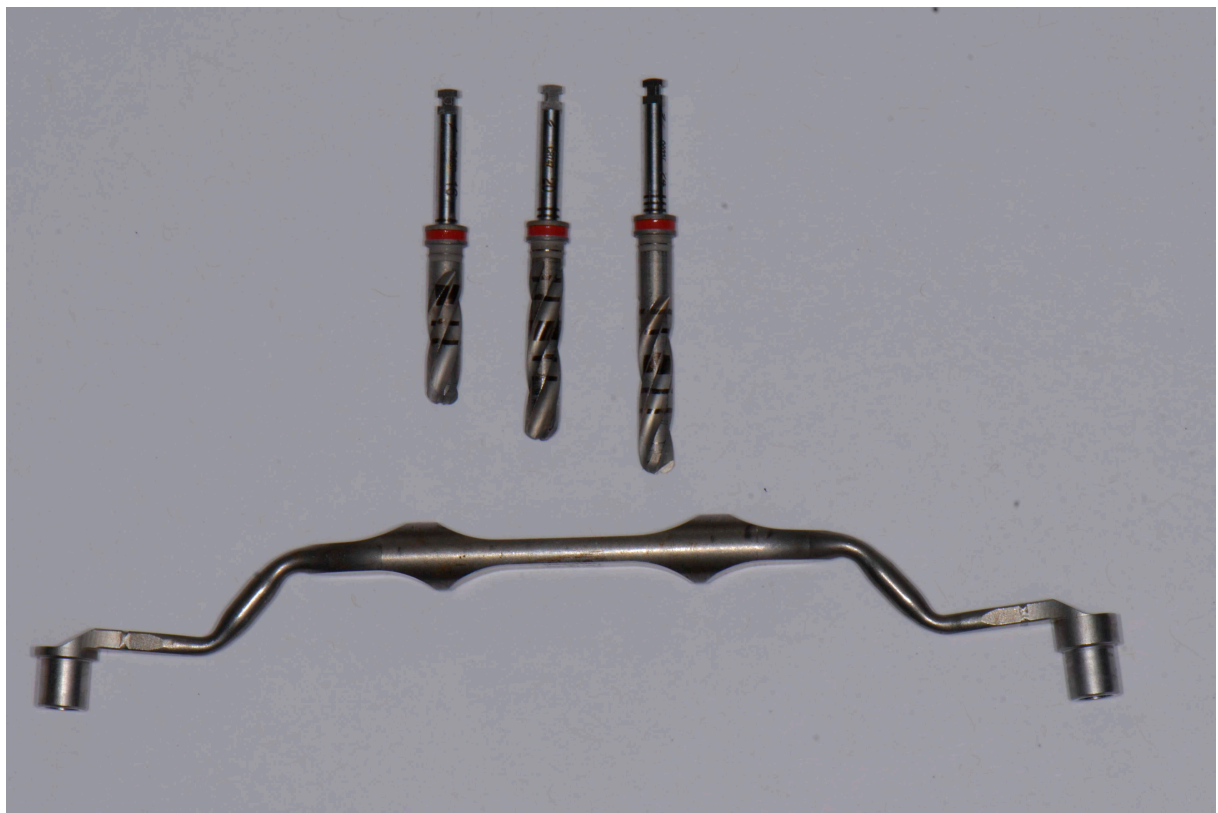


Figure 3: Surgical system used in control 2 and test 2 group: Drills of 16, 20 and 24 mm in length and drill guides of 1 and 3 millimeters in height were used.

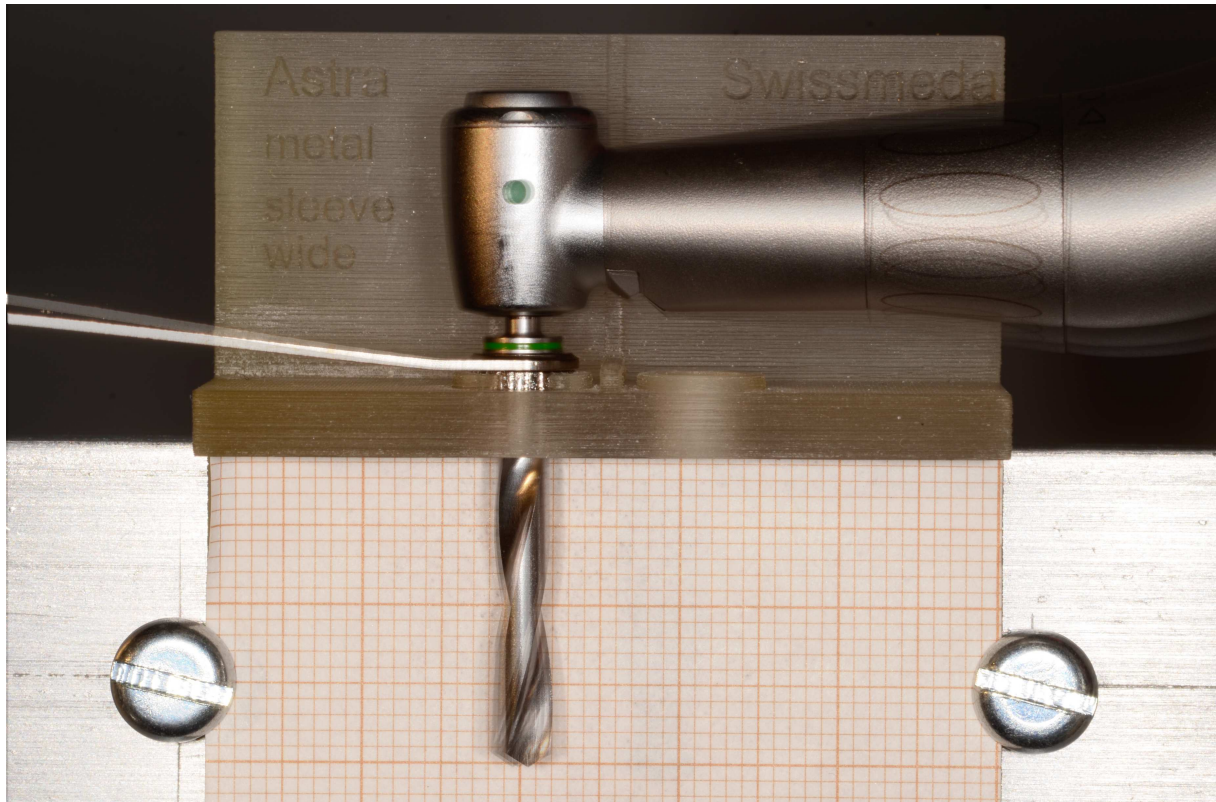


Figure 4: Superimposed images showing lateral movement of drill, group C1. Drill diameter 3.2mm, drill key height 1mm, drill length 25mm

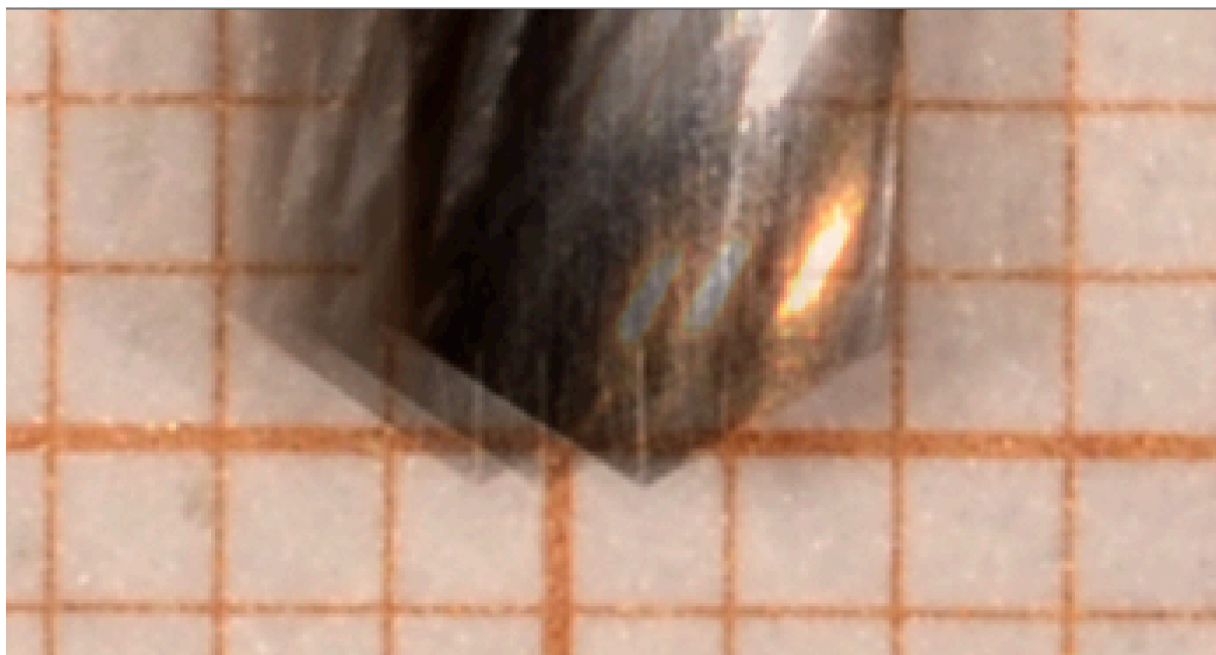


Figure 5: Superimposed images showing lateral movement of drill, group C1, detail.

Magnification x25.

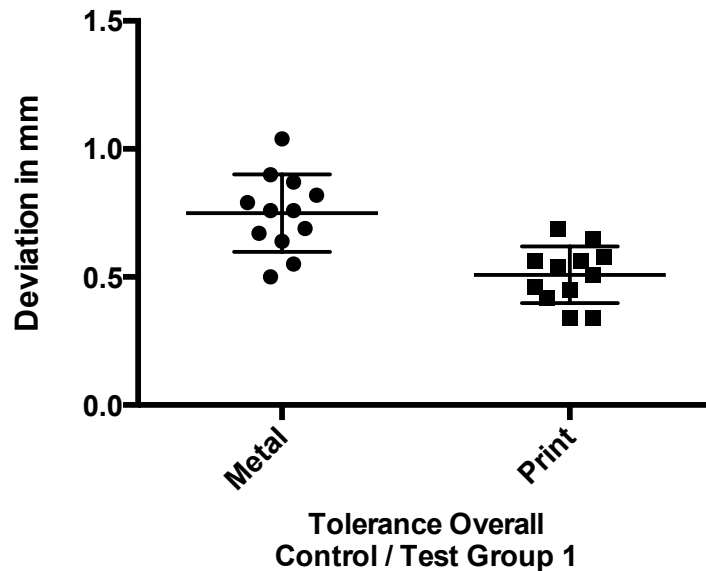


Figure 6: Overall instrument tolerance (drill within drill key and drill key within sleeve) in millimeters, measured as lateral movement of the drill tip. The chart includes the movement for all lengths of drills and drill keys in each group. Control 1 group on the left and test 1 group on the right. The difference between groups is statistically significant ($p < 0.001$)

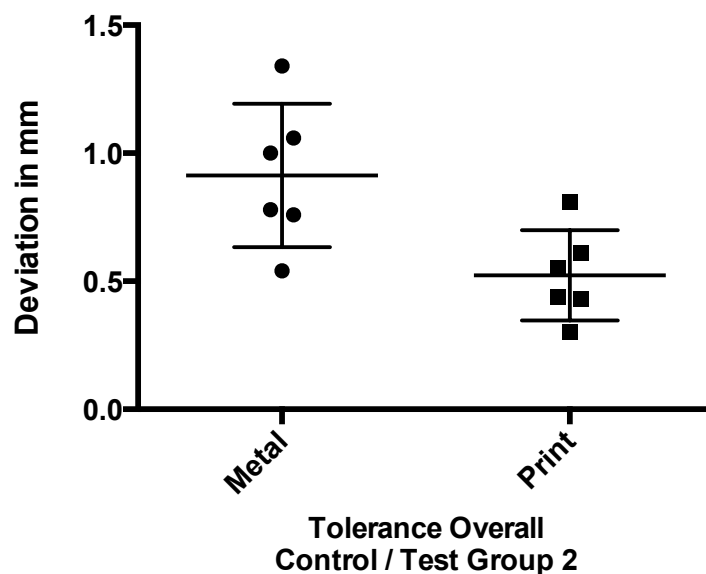


Figure 7: Overall instrument tolerance (drill within drill key and drill key within sleeve) in millimeters, measured as lateral movement of the drill tip. The chart includes the movement

for all lengths of drills and drill keys in each group. Control 2 group on the left and test 2 group on the right. The difference between groups is statistically significant ($p=0.03$)

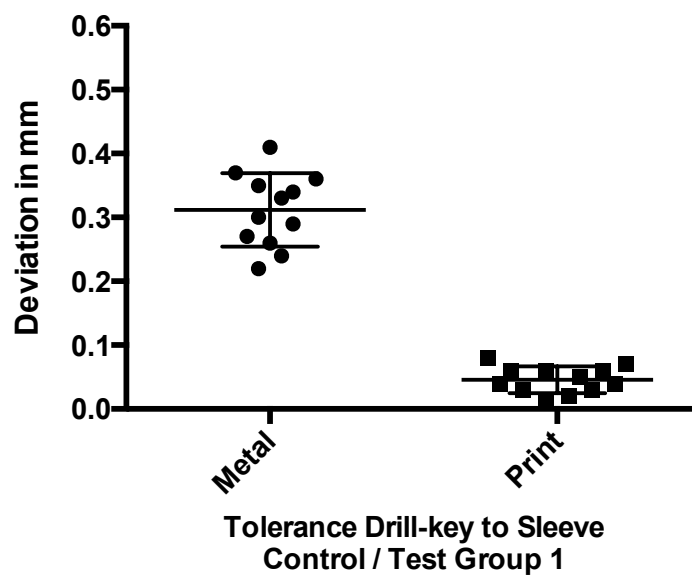


Figure 8: Instrument tolerance resulting from movement of drill key within sleeve in the control 1 group (left) and test 1 group (right). ($p<0.001$)

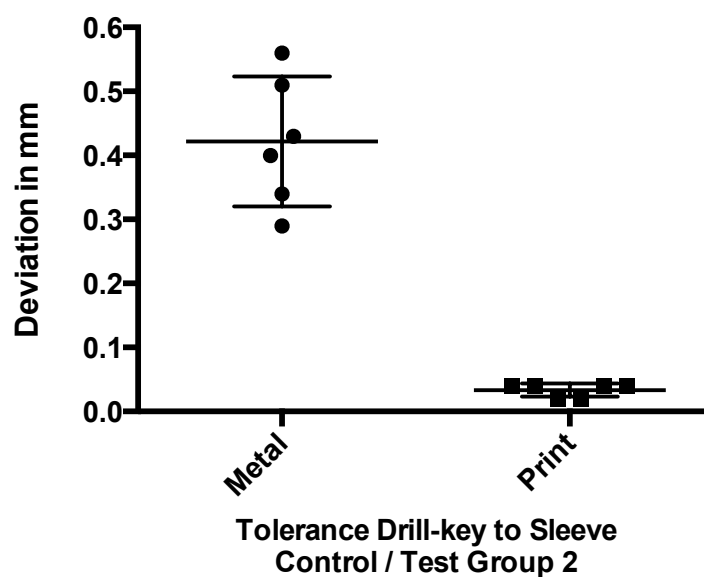


Figure 9: Instrument tolerance resulting from movement of drill key within sleeve in the control 2 group (left) and test 2 group (right). ($p < 0.001$)

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